UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte PAUL C. ANDERSON, PAUL S. CHOMET, MATTHEW C. GRIFFOR, and ALAN L. KRIZ

Appeal No. 2006-0102 Application No. 09/732,439

ON BRIEF

MAILED

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PAT. & T.M. OFFICE BOARD OF PATENT APPEALS AND INTERFERENCES

Before SCHEINER, ADAMS, and GRIMES, <u>Administrative Patent Judges</u>.

ADAMS, <u>Administrative Patent Judge</u>.

DECISION ON REQUEST FOR REHEARING

Appellants request reconsideration (Request) of the Board's decision entered August 31, 2006 (Decision), wherein the rejection of claim 59 under the written description provision of 35 U.S.C. § 112, first paragraph was affirmed.¹ Claims 60-63, 72, and 73 fell together with claim 59. Appellants present two arguments for our consideration. We take each in turn.

¹ The rejections under 35 U.S.C. § 112, second paragraph, § 102(e), and § 103 were reversed. Having disposed of all claims under the written description provision of 35 U.S.C. § 112, first paragraph, we did not reach the rejection under the enablement provision of 35 U.S.C. § 112, first paragraph.

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1. Is our Decision legally inconsistent with the holding of <u>Capon v. Eshhar</u>, 418 F.3d 1349, 76 USPQ2d 1078 (Fed. Cir. 2005)?

Appellants argue that the affirmance of the written description rejection "is legally inconsistent with the holding of <u>Capon v. Eshhar</u>." Request, page 2.² According to appellants (Request, pages 3-4), "[t]he Board relied extensively on the holding in <u>University of California v. Eli Lilly and Co.</u>, 119 F.3d 1559[, 43 USPQ2d 1398] (Fed. Cir. 1997) . . . [yet] failed to acknowledge that the facts and holding of <u>Lilly</u> are inapposite to the present case, as vividly demonstrated in <u>Capon</u>." In support of this assertion, appellants assert that

Lilly concerned a gene that "had never been characterized." . . . In contrast, the current application does not claim nucleic acids and the novelty of the invention does not turn on the DNA sequences allegedly non-disclosed, which were known in the art. Rather, the invention lies in the expression of known DNA sequences in a monocot plant to confer drought tolerance.

Request, page 4. We disagree with appellants' characterization of their invention. More specifically, we disagree with appellants' assertion that they "are not claiming novel nucleic acids, but rather are claiming an invention that makes use of known sequences." Request, page 5. We also disagree with appellants'

² We remind appellants as explained in section 1206 of the Manual of Patent Examining Procedure (8th ed., rev 2, May 2004) (MPEP), emphasis added:

³⁷ C[.]F[.]R[. §] 1.192(a) is not intended to preclude the filing of a supplemental paper if new authority should become available or relevant after the brief was filed. An example of such circumstances would be where a pertinent decision of a court or other tribunal was not published until after the brief was filed.

Here, appellants simply assert that <u>Capon</u> was not cited or relied upon prior to the Decision because <u>Capon</u> did not publish until after the briefs were filed. It remains unclear why appellants did not file a supplemental paper in the one year period between the publication of the <u>Capon</u> opinion (August 12, 2005) and the Board's August 31, 2006 Decision. Particularly when they believe that "[t]he present case involves issues that are more analogous to those in <u>Capon</u>, rather than those in <u>Lilly</u>." Request, page 5.

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assertion that the court in <u>Capon</u> was "faced with facts similar to those in the present case" Request, page 6.

For clarity we reproduce claim 59 below:

59. A transformed monocot plant, which plant is substantially tolerant or resistant to a reduction in water availability, the cells of which comprise a recombinant DNA segment comprising a preselected DNA segment encoding an enzyme which catalyzes the synthesis of the osmoprotectant proline, wherein the enzyme is expressed in an amount effective to confer tolerance or resistance to the transformed plant to a reduction in water availability.

Claim 59 is drawn to a transformed monocot plant. The cells of the plant comprise a recombinant DNA segment. The recombinant DNA segment comprises a preselected DNA segment encoding an enzyme which catalyzes the synthesis of the osmoprotectant proline. This enzyme is expressed in an amount effective to confer tolerance or resistance to the transformed plant to a reduction in water availability. Thus, the plant is substantially tolerant or resistant to a reduction in water availability.

According to appellants, they "are not claiming novel nucleic acids, but rather are claiming an invention that makes use of known sequences." Request, page 5. If this were true, appellants' arguments regarding <u>Capon</u> might be more applicable. Claim 59, however, is not so limited. To the contrary, claim 59 requires a "recombinant DNA segment [that] comprises a preselected DNA segment encoding an enzyme which catalyzes the synthesis of the osmoprotectant proline." As we explained at page 7 of the Decision,

the examiner finds (Answer, page 15), the phase "recombinant DNA segment encoding an enzyme which catalyzes the synthesis of the osmoprotectant proline" encompasses a genus of DNAs "of any sequence", "obtained from any source", "encoding any enzyme

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of any type", "which catalyzes the synthesis of the osmoprotectant proline." According to the examiner (Answer, bridging sentence. pages 15-16), appellants' specification does not disclose or refer to any DNA segment or enzyme within this genus.

In addition, we pointed out the examiner's finding that "[g]iven that proline is an amino acid found in virtually all organisms, a variety of structurally and functionally distinct proline biosynthetic enzymes exist that are encoded by genes from divergent plant, animal and microbial species."

Appellants' Request does not address these findings. Instead, appellants assert that they "are not claiming novel nucleic acids, but rather are claiming an invention that makes use of known sequences." Request, page 5. According to appellants (Request, bridging sentence, pages 5-6), "[t]he Board acknowledges in the present case that at least two genes for use with the invention were known " More accurately, we stated "[a]t best, appellants have established that two such genes, Δ^1 -pyrroline-5-carboxylate synthetase and [human] pyrroline-5-carboxylate reductase, were known in the art at the time their invention was made." Decision, page 12. Had claim 59 been limited to these two genes, we would have agreed that "since 'these sequences were known to those of skill in the art at the time of filing, [a]ppellants cannot be said to lack written description for these sequences." Decision, page 8. Here, as in Capon, requiring appellants to reiterate in their specification the structure or formula of known DNA sequences having a known function does not add descriptive substance. Capon 418 F.3d at 1358, 76 USPQ2d at 1085. The problem is, however, that claim 59 is not limited to these sequences and appellants' specification does not adequately support the breadth of the genus

encompassed by claim 59. In this regard, we direct appellants' attention to the second part of <u>Capon</u>, specifically discussing the relationship between the scope of the claim and the written description requirement. <u>Capon</u>, 418 F.3d at 1358-1361, 76 USPQ2d at 1085-1087.

As discussed at page 9 of the Decision, "the evidence of record establishes that as of appellants' filing date three distinct pathways were known to exist for the production of proline." Notwithstanding the "three separate pathways for the biosynthesis of proline, which appear to utilize a number of different enzymes, appellants would assert that the knowledge in the art of P5CS and P5CR is representative of the entire genus of enzymes involved in proline biosynthesis." Id. We disagree. In this regard, we note that "[a]ppellants fail to direct our attention to any evidence of record . . . that teaches the enzymes involved in the third pathway for proline biosynthesis, which involves the intermediate ornithine." Id.

For the foregoing reasons, as well as those set forth in the Decision, we disagree with appellants' assertion that "the facts and holding of <u>Lilly</u> are inapposite to the present case, as vividly demonstrated in <u>Capon</u>." Request, bridging sentence, pages 3-4. As set forth in Capon

[i]t is well recognized that in the "unpredictable" fields of science, it is appropriate to recognize the variability in the science in determining the scope of the coverage to which the inventor is entitled. Such a decision usually focuses on the exemplification in the specification. See, e.g., Enzo Biochem, 296 F.3d at 1327-28 (remanding for district court to determine "[w]hether the disclosure provided by the three deposits in this case, coupled with the skill of the art, describes the genera of claims 1-3 and 5"); Lilly, 119 F.3d at 1569 (genus not described where "a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of

the genus" had not been provided); <u>In re Gosteli</u>, 872 F.2d 1008, 1012 (Fed.Cir.1989) (two chemical compounds were insufficient *1359 description of subgenus); <u>In re Smith</u>, 59 C.C.P.A. 1025, 458 F.2d 1389, 1394-95 (1972) (disclosure of genus and one species was not sufficient description of intermediate subgenus); <u>In re Grimme</u>, 47 C.C.P.A. 785, 274 F.2d 949, 952 (1960) (disclosure of single example and statement of scope sufficient disclosure of subgenus).

On reflection, it is our opinion that our analysis, and the precedent relied upon in the Decision is correct. For the reasons set forth above and in our Decision, we are not persuaded by appellants' arguments and reliance on Capon. Accordingly, we reaffirm the rejection of claim 59 under the written description provision of 35 U.S.C. § 112, first paragraph. Claims 60-63, 72, and 73 fall together with claim 59.

2. Should appellants' request for rehearing be granted to review a reference that is not of record in the case without a showing of good and sufficient reasons why it was not earlier presented?

According to appellants "the [e]xaminer in this case was <u>obligated</u> to take into account the level of skill and knowledge in the art." Request, page 7.

Accordingly, appellants assert that the examiner should have considered Williamson³, which was not made of record, "in addition to the numerous other references cited in the [a]ppellants' Appeal Brief" Id.

According to appellants (Request, page 8), "[t]he fact that a specific reference was not of record does <u>not</u> change the fact that the reference was known at the time of filing of the application. Therefore, the reference is pertinent to an evaluation of the written description requirement and must be

³ Williamson et al. (Williamson), "Molecular Cloning and Evidence for Osmoregulation of the Δ1-Pyrroline-5-Carboxylate Reductase (<u>pro</u>C) Gene in Pea (<u>Pisum sativum L.</u>)," <u>Plant Physiol.</u>, Vol. 100, pp. 1464-1470 (1992).

considered." In this regard, appellants assert that the Board "is required to determine whether the [e]xaminer applied the correct legal standards" Request, page 7.

At page 5 of their Reply Brief, appellants acknowledge that Williamson was "not entered on the record. . . . " More specifically, the examiner finds (Answer, page 17), Williamson "is not disclosed in the specification, was not made of record in an information disclosure statement, and was not made of record in previous responses." Stated differently, this reference was relied upon for the first time in the Brief. In this regard, we direct appellants' attention to 37 C.F.R. § 41.33(d)(2), which states "[a]|| other affidavits or other evidence filed after the date of filing an appeal pursuant to § 41.31(a)(1) through (a)(3) will not be admitted except as permitted by §§ 41.39(b)(1), 41.50(a)(2)(i) and 41.50(b)(1)."

On reflection, appellants admit that Williamson was available and "known" prior to appellants' filing date; that Williamson is relevant to the subject matter at issue; and that Williamson was not made of record in the case. Since appellants failed to properly make the reference of record in this case we deny appellants' request for rehearing to consider Williamson.

We have carefully reviewed the original opinion in light of appellants' request, but we find no point of law or fact which we overlooked or misapprehended in arriving at our decision. Accordingly, appellants' request has been granted to the extent that the decision has been reconsidered, but such

request is denied with respect to making any modifications to the decision affirming the rejection under the written description provision of 35 U.S.C. § 112, first paragraph.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

REHEARING DENIED

Toni R. Scheiner

Administrative Patent Judge

) BOARD OF PATENT

Donald E. Adams

Administrative Patent Judge

APPEALS AND

INTERFERENCES

Eric Grimes

Administrative Patent Judge

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